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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PONNALURI, PADMASHRI

ART UNIT PAPER NUMBER

1639

DATE MAILED: 11/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/351,617

Applicant(s)

Mehta et al

Examiner

Padmashri Ponnaluri

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 12, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 6, 12-20, 23, 24, 26, 27, and 31-35 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6, 12-20, 23, 24, 26, 27, and 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

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DETAILED ACTION

NOTE: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1639.

1. The amendment and the response filed on 9/12/02 has been fully considered and entered into the application.
2. Claims 1, 6, 12-20, 23-24, 26-27, 31-35 are currently pending in this application.
3. Applicant is invited to notice that boxes 5, 10 and 12 were checked by the draftsman. If applicants renumber the figures, applicant is encouraged to amend the specification so that the description of renumbered figures corresponds to the renumbered figures.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. The rejection of claims 1, 6, 12-20, 23-24, 26-27, 31-35 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, has been maintained for the reasons of record set forth in the previous office action mailed on 3/12/02.

Claims 1 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: showing that the bond between hybrid ligand A and the predetermined target is a irreversible (covalent) bond. The claims are

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missing an essential element which shows that the bond between the ligand A and the predetermined target is irreversible. The specification does not show that the bond is irreversible or how to determine that the bond is irreversible.

6. Claims 1, 6, 12, 17, 19, 20, 23-24, 31-32, 35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Licitra et al (Proc. Natl. Acad. Sci. USA., vol. 93, pp. 12817-12821, November 1996) are rejected for the reasons of record set forth in the previous office action mailed on 3/12/02.

7. Claims 1, 6, 12, 17, 19, 20, 23-24, 31 and 35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent 5,928,868 (Liu et al) for the reasons of record set forth in the office action mailed on 3/12/02.

New Rejections Necessitated by the Amendment

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 31 and 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection..

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The newly deleted limitation “covalent” and “covalently” in Claims 1, 31 and 35 has no clear support in the specification and the claims as originally filed. Now the amended claims recite that ‘ligand A forms an irreversible bond with the predetermined target’, and open to other kinds of irreversible bonds, not only covalent bonds. The newly deleted subject matter in claims 1, 31 and 35 broadens the scope of the invention as originally disclosed in the specification.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

Response to Arguments

10. *Applicant's arguments filed on 9/12/02 regarding the 112, second paragraph rejection have been fully considered but they are not persuasive.*

A) Applicants arguments regarding ‘small molecule’ have been considered. Applicants have pointed out the specification page 14 for the definition of ‘small molecule’, however the specification page 15 has the disclosure. It seems that Applicants copy of the specification and the instant application specification copy in the office does not seem to be the same.

Applicants arguments regarding the ‘small molecule’ have been fully considered and the rejections have been withdrawn.

B) Applicants argue that the specification discloses that the bond between the ligand A and the target is irreversible. Applicants support the arguments by referring to the Figure 3, in which mechanism of Aspirin and its analogs form a irreversible (covalent) bond with cyclooxygenase;

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and the specification in page 9, teaches that aspirin and antibiotics have specificity to cyclooxygenase and peptidoglycan transpeptidase, to form irreversible (covalent) bond with their target by acetylation of the amino acid residues, serine hydroxyl group.

Applicants arguments have been fully considered but are not persuasive, because the specification disclosure is drawn to specific ligand and target interactions and further the specification does not disclose how or why the bond between aspirin (ligand) and cyclooxygenase (target) is considered as irreversible covalent. The bond between the ligand and the target can be covalent irreversible or reversible based on several factors. The specification does not disclose the specific conditions required for the 'irreversible covalent' bond formation between the ligand A and target.

Applicants further argue that the regarding the KD values of the bond between the ligand and the target. Applicants refer to page 17 of the specification. However, the instant specification page 18 discloses in general, “ the affinity of a ligand or small molecule for a target molecule may vary substantially in the chemical hybrid screen.” not in respect to the instant method.

Thus, for the reasons of record the rejections of record have been maintained for the reasons of record.

11. Applicant's arguments filed on 9/12/02, regarding the rejections over Licitra et al and Liu et al (US Patent 5,928,868) have been fully considered but they are not persuasive.

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Applicants arguments have been fully considered but is not persuasive. Applicants argue that the instant specification discloses that how the bond between the ligand A and the target is irreversible. Applicants in support of this arguments refer to the specification page 9, which teaches that 'aspirin and antibiotics have specificity to cyclooxygenase and peptidoglycan transpeptidase, to form irreversible (covalent) bond with their target by acetylation of the amino acid residues, serine hydroxyl group.'. Applicants arguments have been fully considered and are not persuasive, since the instant claims neither recite a specific ligand A, nor specific target. And further the instant claims do not recite how the bond formed between the ligand A and the target (i.e., acetylation of the amino acid residues, serine hydroxyl group).

And further Figure 3 of the instant specification refers to the mechanism of Aspirin and its analogs with cyclooxygenase. Neither the figure nor the description of the figures disclose that the bond is irreversible covalent. And even then the instant claims are not drawn to the bond formation between aspirin or analogues and the cyclooxygenase in particular, and especially the not the acetylation of the amino acid.

Applicants further assert that the formation of the irreversible bond between the ligand A, and the target results in a method which is different from the prior art method of Licitra and Liu, which teach reversible bonds between the target and the ligand.

Applicants arguments have been considered but are not persuasive, since the reference teaches exactly same method steps as the instant claims. Applicants have not shown how and why the bond between the ligand A and the target of the instant claimed method is different from

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the prior art. Applicants have not distinguished either structure of the target or the ligand or the experimental conditions in which the bond between the target and the ligand such that the bond between the ligand and target would result in a different bond compared to the reference teachings.

Applicants further argue that the reference Liu and Licitra three-hybrid system results in numerous positive results. Applicants arguments have been considered but are not persuasive, since the arguments are irrelevant regarding the 'irreversible covalent bond formation'. Further applicants argue in view of the later published documents, which would not discuss whether the bond formed between the ligand A and the target are irreversible or reversible covalent bond.

*In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., KD values less than 10^{-15} and use of lower concentrations of the hybrid ligand) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).*

Applicants further argue the 'improvements' or the 'unexpected results' of the instant method compare to the reference method. In support for these arguments applicants refer to articles published much later and have not shown how the instant method is improvement over the prior art. The rejections of record have been maintained

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12. No claims are allowed.
13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on *Increased Flex Schedule* and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Patent Examiner
Technology Center 1600
Art Unit 1639
21 November 2002


PADMASHRI PONNALURI
PRIMARY EXAMINER